



Food and Drug Administration  
**OFFICE OF CRIMINAL INVESTIGATIONS**  
**MEMORANDUM OF INTERVIEW**

**CASE NUMBER:** [REDACTED]  
**CASE TITLE:** THERANOS, INC.  
**DOCUMENT NUMBER:** [REDACTED]  
**PERSON INTERVIEWED:** Audra Zachman  
**PLACE OF INTERVIEW:** [REDACTED]  
**DATE OF INTERVIEW:** 06/14/2019  
**TIME OF INTERVIEW:** 10:15 AM PST  
**INTERVIEWED BY:** ASAIC George Scavdis

**OTHER PERSONS PRESENT:** See below

On June 14, 2019, the case agent interviewed Audra Zachman, nurse practitioner, Southwest Contemporary Women's Care (SCWC), at their office in Tempe, Arizona, regarding Theranos, Inc. Also present during the interview were the following: John Bostic, Assistant United States Attorney (AUSA), United States Attorney's Office for the Northern District of California (USAO/NDC), San Jose Division; Robert Leach, AUSA, USAO/NDC, Oakland Division; and Matthew Norfleet, Special Agent, United States Postal Inspection Service.

Ms. Zachman obtained her Doctorate degree in nursing practice in 2013. Her mother was a nurse practitioner at SCWC, and Ms. Zachman became a nurse practitioner specifically to work in that same office. SCWC was the first place that Ms. Zachman went to work. She went to undergraduate school at Arizona State University, and she started working at SCWC in July 2013.

SCWC has a product committee, of which Ms. Zachman was the head. The purpose of the product committee was to funnel medical sales representatives to Ms. Zachman. The product committee covered all three office locations. A Theranos sales representative dropped off paperwork that went to Ms. Zachman as head of the product committee for her to review. The product committee would filter through requests from companies and then they would meet to compare the competing companies. The main concerns of the product committee were validity, cost, and accessibility. At the time that Ms. Zachman was head of the product committee, there were a total of three people on the committee. Eventually, Courtney Domingo took over for Ms. Zachman as head of the product committee.

Ms. Zachman explained that when the product committee is assessing a drug or device's validity, they are making sure that it is FDA approved and that the testing process has been validated. In terms of laboratory testing, validity would mean that the test is accurate. Validity or accuracy is probably the most important factor when considering a testing laboratory.

Ms. Zachman remembers that the Theranos sales representative came in and gave an e-mail contact. The technology was presented as being "new age". It was presented as being cheaper and as being something that patients could pay cash for if they didn't have insurance. This information was presented at the beginning of Theranos's engagement with the practice.

AUSA Bostic showed Ms. Zachman an e-mail dated June 20, 2014, titled "RE: theranos" bates numbered

LINNERSON-001131 (attachment one). The name Peggy Shuffler is familiar to her. Ms. Zachman's initial contact with Theranos was probably a few days prior to this e-mail.

AUSA Bostic showed Ms. Zachman an e-mail dated July 14, 2014, titled "product committee" bates numbered LINNERSON-000427 (attachment two). She explained that the product committee evolved over the years. This may have been before each office had a representative on the committee. In this e-mail, the product committee is setting up a meeting to have three different testing laboratories come in and present to it. GenPath does blood testing, PAPs, and pathology testing. SCWC was using Sonora Quest and LabCorp. prior to engaging Theranos. GenPath and Theranos were being auditioned to replace Sonora Quest.

AUSA Bostic showed Ms. Zachman an e-mail dated September 5, 2014, titled "RE: theranos- product committee" bates numbered LINNERSON-000451 (attachment three). Ms. Zachman explained that there aren't many testing laboratories, so it wouldn't have been hard for one to get in front of the product committee. She remembers seeing Elizabeth Holmes on the front of a magazine in the airport and feeling proud that SCWC was partnered with Theranos. This e-mail chain would have been after the product committee's meeting with Theranos. Theranos provided marketing materials in hardcopy form to the product committee, which Ms. Zachman eventually disposed of. Theranos didn't provide the documents in electronic form.

Theranos told Ms. Zachman that their testing was valid, less expensive, that they were able to use less blood, and that it was more convenient. Theranos also pitched their ability to integrate with SCWC and provide an in-house phlebotomist. They touted their finger stick test and said that patients were more likely to have their blood drawn as a result. Ms. Zachman doesn't recall Theranos showing her photos of their devices. They may have shown her a picture of the blood collection vial, but they never showed her a picture of their blood analyzer. Ms. Zachman feels like they proposed that all their testing could be done via finger stick method during their initial pitch to the product committee. Later, they said not all their tests would be available via finger stick blood draw method. She doesn't recall Theranos making representations about their technology having FDA approval. Ms. Zachman doesn't recall how many people from Theranos presented to the product committee.

AUSA Bostic directed Ms. Zachman back to attachment three. She said she doesn't recall this meeting happening or the details of it. SCWC probably started using Theranos for patient testing before having them provide an in-house phlebotomist.

B■■■■ G■■■■ was not an IVF patient, and Ms. Zachman was not her treating doctor during her previous pregnancies. AUSA Bostic directed Ms. Zachman to an e-mail dated April 25, 2018, titled "FW: Theranos" bates numbered LINNERSON-001077 through 001078 (attachment four). Ms. Zachman said that Theranos was available to perform testing on the weekends and Sonora Quest was not, so that might explain why Sonora Quest was chosen for Ms. G■■■■ to be tested before Theranos. Ms. Zachman would have confirmed Ms. G■■■■'s pregnancy with a urine test in the office, and then would have ordered blood laboratory tests for her based on Ms. G■■■■'s history of miscarriages. An HCG value of 1805 tells you that pregnancy has occurred. It doesn't speak to the viability of the pregnancy, but it's a "very positive" result in terms of whether a pregnancy has occurred. It is normal to send a patient who has had previous miscarriages for HCG testing every 48 hours. Ms. G■■■■ was tested by Theranos twice. The two different results had the same value, but the decimal place had moved. A normal health pregnancy will see the HCG value double every 48 hours. It's improbable that the digits for the value would stay the same and just have the decimal place move (i.e. 1,200 vs. 120)

AUSA Bostic directed Ms. Zachman two documents: a Theranos test result bates numbered LINNERSON-001083 and one bates numbered LINNERSON-001085 (attachment five). Ms. Zachman recalls reaching out to Ms. G■■■■ to prepare her that her pregnancy was lost. Ms. Zachman was suspicious of such a large drop in HCG value over a 48-hour period. She would have expected that to be accompanied by significant bleeding, but it was not. Her conversation with Ms. G■■■■ was a difficult conversation to have. This visit with Ms. G■■■■ was important because once a patient has had a fourth miscarriage, that patient is put in a category called "recurrent pregnancy loss", which means that something is going on in the patient's body that is preventing

her from carrying a baby to term. Ms. Zachman ordered additional testing after the Theranos blood test to confirm that a miscarriage had occurred.

ASUA Bostic directed Ms. Zachman to a lab result report bates numbered LINNERSO-001094 (attachment six). She said that this result is a sure signal of pregnancy. This result caused confusion and embarrassment. She didn't know which result to dismiss at this point. It was at this point that Ms. Zachman started to distrust the Theranos test result. She had never had an unreliable HCG result prior to the Theranos test. In fact, she finds HCG to be a reliable test that laboratories get right. HCG is not a test whose value goes up, and then down, and then back up again. Ms. Zachman wanted Ms. G[REDACTED] to repeat the HCG test. After that repeat, she was eligible for an ultrasound examination. Ms. Zachman was vocal within SCWC about what happened with Ms. G[REDACTED]'s Theranos HCG test. She called Theranos to speak with their complaint department, and this led her to send e-mails to Theranos.

AUSA Bostic directed Ms. Zachman to an e-mail dated October 14, 2014, titled "Checking Back" bates numbered LINNERSO-001214 (attachment seven). The Theranos employee in this e-mail, Leslie, is trying to arrange a telephone call with Christian Holmes. Ms. Zachman recalls speaking to someone from Theranos on the telephone about filing a formal complaint about their HCG test. The Theranos response to her was very vague. They responded that the error was a simple laboratory error, that it was a decimal point issue, and that the issue would be addressed. Ms. Zachman said that seeing the exact same value one day and then again two days later would be unlikely and troubling. Theranos's explanation was not plausible to her. She remembers that Theranos said they would get back to her.

AUSA Bostic directed Ms. Zachman to an e-mail dated October 29, 2014, titled "Theranos Lab" bates numbered LINNERSO-001219 (attachment eight). Ms. Zachman recalls this e-mail. She was part of the decision to send this e-mail. She doesn't recall additional telephone calls with Theranos in the weeks following this e-mail. At this time in April, SCWC was still using Theranos for testing but was keeping a watchful eye. Ms. Zachman recalls other inaccuracies with Theranos test results, but none of them were for patients of hers.

AUSA Bostic directed Ms. Zachman to an e-mail dated April 24, 2015, titled "RE: meeting" bates numbered LINNERSO-001268 through 001269 (attachment nine). Ms. Zachman doesn't recall this conversation with Mike Phebus. She thinks this was sent around the time the SCWC study of Theranos was discussed.

AUSA Bostic directed Ms. Zachman to an e-mail chain dated July 16, 2015, titled "FW: SW Contemporary Study" bates numbered LINNERSO-000534 through 000541 (attachment ten). Ms. Zachman said that she was skeptical of Theranos, but hopeful at the time that SCWC proposed doing a study. This was the first time the study was being put together. The idea to conduct a study of Theranos against other testing laboratories was likely a collaborative decision made between her, Ms. Domingo, and Dr. Stephen Linnerson. The goal of the study was to restore SCWC's faith in Theranos's "quants". They decided that the study should be a side by side one. SCWC decided that was what they wanted before they proposed it to Theranos. The plan for the study was to, in-house, compare finger stick draws versus venous draws from two other laboratories and Theranos for any patient that was willing to participate. Ms. Zachman doesn't recall speaking to anyone from Theranos with a medical background about the study. She wasn't a part of the decision to compare Theranos to two laboratories as opposed to one.

Ms. Zachman said, "An OBGYN practice should be able to tell a patient if they're pregnant or not." Regarding Ms. G[REDACTED], if Ms. Zachman had relied on the Theranos result and initiated the treatment protocol for a miscarriage, it is very likely Ms. Zachman would have terminated a viable pregnancy.

AUSA Bostic directed Ms. Zachman to an e-mail dated July 29, 2015, titled "Theranos study" bates numbered LINNERSO-000559 (attachment eleven). Ms. Zachman was less involved with the study at this point. She wouldn't have been steering patients to Theranos for testing at this point. She doesn't recall patients being vocal about receiving venous draws instead of finger stick draws from Theranos. Ms. Domingo made a presentation to SCWC on the results of the study.

AUSA Bostic directed Ms. Zachman to an e-mail dated August 27, 2015, titled "Theranos Study" bates numbered LINNERSO-000578 (Attachment twelve). Ms. Zachman explained that these are the results that the study yielded. She didn't draft the chart that has the results. She doesn't remember conversations that were had where the data was reviewed. The conclusion of the practice was to be more vocal about not using Theranos. The study was a part of that decision. Ms. Zachman's experience with Ms. G [REDACTED] had a big impact on her advocacy that others should be skeptical of Theranos and not use them. Ms. Zachman has never had any other problems with HCG tests and other laboratories aside from her experience with Ms. G [REDACTED] and Theranos.

**SUBMITTED:** Electronically submitted by GEORGE SCAVDIS

GEORGE SCAVDIS, ASSISTANT SPECIAL AGENT IN  
CHARGE

DATE: 07/15/2019

**APPROVED:** Electronically approved by MARK MCCORMACK

MARK MCCORMACK, SPECIAL AGENT IN CHARGE

DATE: 07/15/2019

**DISTRIBUTION:** Orig: MWFO w/attachments  
cc: Prosecution w/attachments

**ATTACHMENTS:** 1-an e-mail dated June 20, 2014, titled "RE: theranos" bates numbered LINNERSO-001131  
2-an e-mail dated July 14, 2014, titled "product committee" bates numbered LINNERSO-000427  
3-an e-mail dated September 5, 2014, titled "RE: theranos- product committee" bates numbered LINNERSO-000451  
4-an e-mail dated April 25, 2018, titled "FW: Theranos" bates numbered LINNERSO-001077 through 001078  
5-a Theranos test result bates numbered LINNERSO-001083 and one bates numbered LINNERSO-001085  
6-a lab result report bates numbered LINNERSO-001094  
7-an e-mail dated October 14, 2014, titled "Checking Back" bates numbered LINNERSO-001214  
8-an e-mail dated October 29, 2014, titled "Theranos Lab" bates numbered LINNERSO-001219  
9-an e-mail dated April 24, 2015, titled "RE: meeting" bates numbered LINNERSO-001268 through 001269  
10-an e-mail chain dated July 16, 2015, titled "FW: SW Contemporary Study" bates numbered LINNERSO-000534 through 000541  
11-an e-mail dated July 29, 2015, titled "Theranos study" bates numbered LINNERSO-000559  
12-an e-mail dated August 27, 2015, titled "Theranos Study" bates numbered LINNERSO-000578